"OGB Poly Care 4"
(7670)
Infant incubator
Service Manual

EC CERTIFICATE

Certificate No 747/MDD

Annex

Infant intensive care incubators
Type ref. OGB Poly Care 1; OGB Poly Care 2; OGB Poly Care 3; OGB Poly Care 4; OGB polytrend.
Trade mark Ginevri

Transport infant incubators
Type ref. Baby Shuttle Normal Care; Baby Shuttle Special Care; Baby Shuttle Intensive Care.
Trade mark Ginevri

Infant warmers
Type ref. IW409; IW509; IW909.
Trade mark Ginevri

Series: IW509 PLUS.
Trade mark Ginevri

Series: Isola Neonatale Type ref. ALHENA PLUS ELEVABILE; ALHENA PLUS FISSA; ALHENA ELEVABILE; ALHENA FISSA.
Trade mark Ginevri

Infant heating mattress
Type ref. Acquatherm.
Trade mark Ginevri

Oxygen analyzers
Type ref. LCD 1000.
Trade mark Ginevri

Oxygen tents
Type ref. Oxytent 1000; Oxytent 2000.
Trade mark Ginevri

Phototherapy lamps in neonatal hyperbilirubinemia
Type ref. IP; IPR; RPR; RPS; D; GN; Bililight.
Trade mark Ginevri

Auxiliary infant warmers
Type ref. Hot Spot.
Trade mark Ginevri

Air compressor for transport incubator

Date: 2004-04-21
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Substitution Date: 2008-02-15

IMQ

This is a translation of the Italian text, which prevails in case of doubts

IMQ S.p.A. I-20138 Milano - Via Quintiliano 43 - tel. 0250731(r.a.) - fax 0250991500 - info@imq.it - www.imq.it
Rea MI 1595884 - Registro Imprese MI 12898410159 - C.F./P.I.: 12898410159 - Capitale sociale 4.000.000 euro.

Dear Customer,

Ginevri thanks you for choosing our firm and the quality of our products.

The longstanding Ginevri traditions of professionalism, reliability and availability will once again prove to be your best reward for entrusting us at Ginevri with your neonatal purchases.

Giorgio Ginevri

GINEVRI s.r.l. – Registered office

Via Giacomo Boni - 00162 Roma

⚠ Warning ⚠

This manual must be carefully read by all personnel who install, use or maintain these units.

The operation of this equipment in accordance with the instructions contained in the user and service manuals, combined with regular service maintenance - performed with Ginevri original spare parts and consumables - will assure the efficiency of our devices and the long lasting quality of their performance and reliability.

Maintenance and service must only be performed by technicians who have been trained and authorized by Ginevri.

GINEVRI S.r.l.- Customer Care Service

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www.ginevri

This manual refers to the enclosed equipment:

OGB Poly Care 4

S/N_____

INDEX

1. CALIBRATION

CALIBRATION CHECK

Check the Temperature, Humidity and Oxygen probes correct operation, at least every three months, in order to make sure of the proper operation of the device and to protect the newborn's health. **The check of the probes reading is done by using the two Reference Simulators, produced by Ginevri s.r.l., that, in case of malfunctioning, are necessary for the re-alignment of the probes.**
The Reference Simulators are optional devices that can be ordered to Ginevri s.r.l., with the part numbers **10487A60** and **10875A60.**
Perform the following steps to check the probes calibration.

TEMPERATURE PROBES

1. Switch the equipment off and disconnect it from the power supply
2. Disconnect the probe assembly connector from the control panel and replace it with the Reference Simulator
3. Connect the equipment to the power supply and switch it on.
4. Set the reference simulator on AIR 1 at 25,0°C (potentiometer PROBES on A1 and potentiometer TEMP °C on 25°C). The temperature display TEMP°C should show the value 25,0°C ± 0,2°C.
5. Set the reference simulator on AIR 1 at 32,0°C. The temperature display TEMP°C should show the value 32,0°C ± 0,2°C.
6. Set the reference simulator on AIR 1 at 33,0°C. The temperature display TEMP°C should show the value 33,0°C ± 0,2°C.
7. Set the reference simulator on AIR 1 at 36,0°C. The temperature display TEMP°C should show the value 36,0°C ± 0,2°C.
8. Set the reference simulator on AIR 1 at 38,0°C. The temperature display TEMP°C should show the value 38,0°C ± 0,2°C.
9. Set the reference simulator on AIR 1 at 40,0°C. The temperature display TEMP°C should show the value 40,0°C ± 0,2°C.
10. Set the reference simulator on AIR 2 at 25,0°C (potentiometer PROBES on A2 and potentiometer TEMP °C on 25°C).. The temperature display TEMP°C should show the value 25,0°C ± 0,2°C.
11. Set the reference simulator on AIR 2 at 32,0°C. The temperature display TEMP°C should show the value 32,0°C ± 0,2°C
12. Set the reference simulator on AIR 2 at 33,0°C. The temperature display TEMP°C should show the value 33,0°C ± 0,2°C
13. Set the reference simulator on AIR 2 at 36,0°C. The temperature display TEMP°C should show the value 36,0°C ± 0,2°C
14. Set the reference simulator on AIR 2 at 38,0°C. The temperature display TEMP°C should show the value 38,0°C ± 0,2°C
15. Set the reference simulator on AIR 2 at 40,0°C. The temperature display TEMP°C should show the value 40,0°C ± 0,2°C
16. Set the reference simulator on MAX TEMP (potentiometer PROBES and deviator on MAX TEMP) and on VAR (potentiometer TEMP °C on VAR), set the potentiometer VAR on 39,0°C and check that MAX TEMP alarm has not been activated. Set the reference simulator on 40,0°C and check that MAX TEMP alarm is activated.

OXYGEN PROBE

17 During normal operation, both in AIR and in SKIN mode, connect the reference simulator oxygen/humidity to the oxigen probe inlet.
18 Adjust the selector of the reference simulator on MEASURE mode.
19 Check that the display % OXIGEN indicates CA blinking.
20 Adjust the selector of the reference simulator on CAL mode and wait for about 30 sec. before doing the calibration.
21 During the calibration, check that CA on the % OXIGEN display is not blinking anymore.
22 When the calibration is finished, check that the % OXIGEN display shows 21%.
23 Set the reference simulator at 98% and check that the % OXIGEN display shows 98% ± 0%.
24 Set the reference simulator at 21% and check that the % OXIGEN display shows 21% ± 0%.

HUMIDITY PROBE

25 Connect the oxygen/humidity reference simulator to the PROBE ASSEMBLY inlet.
26 Check that the led HUMIDITY probe is switched off.
27 Set the reference simulator at 90%. The % HUMIDITY display should show the value 90% ± 0%on
28 Set the reference simulator at 60%. The % HUMIDITY display should show the value 60% ± 0%.
29 Set the reference simulator at 30%. The % HUMIDITY display should show the value 30% ± 0%.

If any malfunction is detected, the probes that have shown a malfunction have to be calibrated. The calibration procedure can be done by means of the same device used for the calibration check and following the procedure below.

AIR 1 PROBE CALIBRATION

The probes calibration has to be performed as follows:

1 Switch the equipment off and disconnect it from the power supply.
2 Disconnect the probe assembly connector from the control panel and replace it with the Reference Simulator.
3 Connect the equipment to the power supply and switch it on.
4 Set the Reference Simulator on AIR 1, MUTE, TEMP =25°C.
5 Set the multimeter on mV voltage in cc and connect the negative terminal on pin 2 of J5 and the positive terminal on TP1 Of the microprocessor board (see related LAYOUT)
6 Adjust the trimmer R29 until the measured value is 1060mV **±** 1mV.
7 Disconnect the multimeter and set the reference simulator on TEMP = 36°C.
8 Adjust the trimmer R28 until the AIR display of the display board shows the value 36,0°C ± 0,2°C.
9 Set the TEMP selector of the reference simulator on each value and check the calibration for all of them, except for 0°C and 40°C, by reading the value shown on the AIR display. Every value must be hold for at least 10 sec. and the following deviations are admitted:

25,0°C ± 0,2°C
29,0°C ± 0,2°C
33,0°C ± 0,2°C
34,0°C ± 0,2°C
36,0°C ± 0,2°C
38,0°C ± 0,2°C

AIR 2 PROBE CALIBRATION

10 Switch the equipment off and disconnect it from the power supply.
11 Disconnect the probe assembly connector from the control panel and replace it with the Reference Simulator.
12 Connect the equipment to the power supply and switch it on.
13 Set the Reference Simulator on AIR 2, MUTE, TEMP = 36°C.
14 Adjust the trimmer R31 until the AIR display of the display board shows the value 36°C ± 0,2°C.
15 Repeat step 9 with the reference simulator for both Air1 and Air2.

MAX TEMP CALIBRATION

16 Set the Reference Simulator on MAX TEMP (potentiometer PROBES and deviator on MAX TEMP), TEMP = 40°C.
17 The MAX TEMP should be active.
18 Adjust the trimmer PT 101 of the display board until the balance point between activation and disactivation of the alarm is reached. Adjust the trimmer so that the alarm is activated.
19 Set the reference simulator on VAR. Rotate the potentiometer on the reference simulator until the alarm is activated, without moving the potentiometer set the reference simulator on AIR1. Check that the Air display shows the value 40.0°C ±0.1°C. Repeat step 18, if needed.
20 Check that at every activation of the alarm MAX TEMP the relay RL2 is disactivated and the led bar showing the heating percentage indicates zero..

SKIN CALIBRATION

21 Set the Reference Simulator on SKIN, MUTE, TEMP = 36°C.
22 Adjust the trimmer R30 until the SKIN display of the display board shows the value 36,5°C ± 0,2°C.
23 Repeat steps 9 to 15 and steps 21 and 22 with the reference simulator for both Air1 and Air2 (the Skin reading has to be seen on the Skin display).

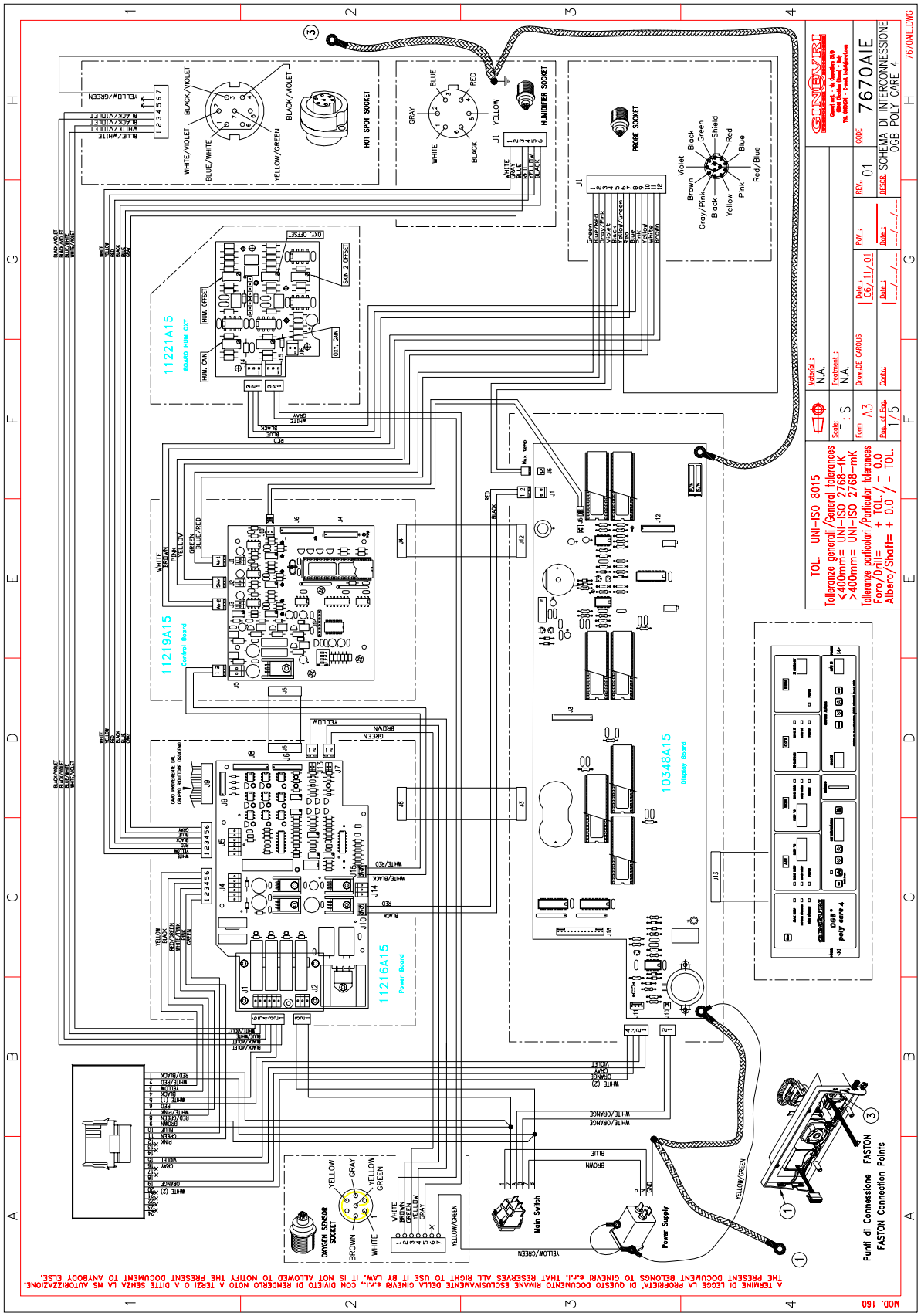
HUMIDITY CALIBRATION

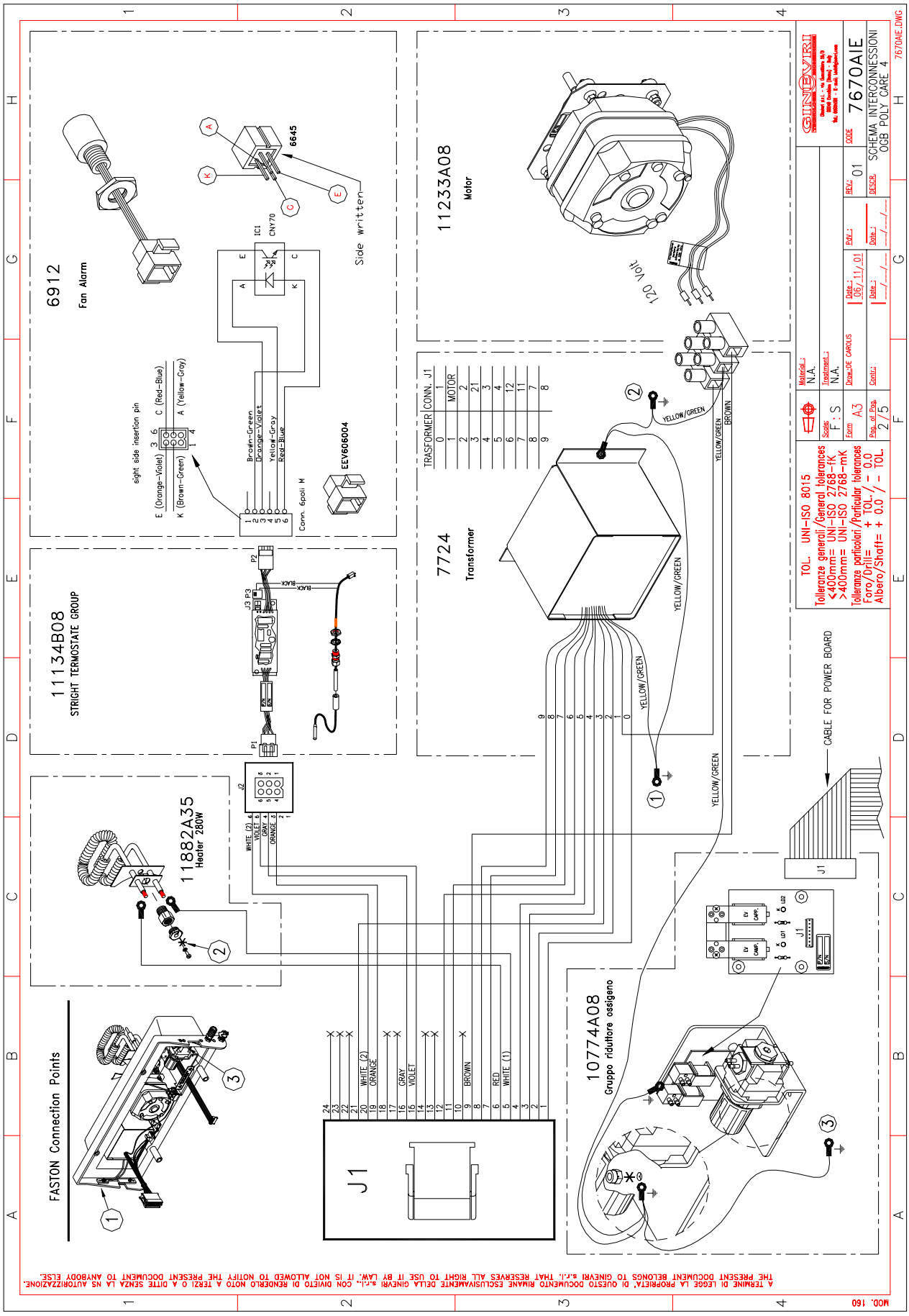
24 Connect the oxygen/humidity reference simulator to the proper connectors placed on the control panel. Set the oxygen/humidity reference simulator on HUM = 0%. Connect the multimeter, select mV cc, with negative terminal on pin 2 and the positive terminal on pin 5 of U12 of the microprocessor board. Adjust the trimmer PT1 placed on the display board until the value measured by the multimeter is 0mV ± 0,2mV.
25 Set the oxygen/humidity reference simulator on HUM% = 90%.
26 Adjust the trimmer PT1 placed on the display board until the HUM display on the display board shows the value 90.
27 Check the calibration on the remaining set values HUM = 30% and HUM = 66%. There is no particular deviation requirement.

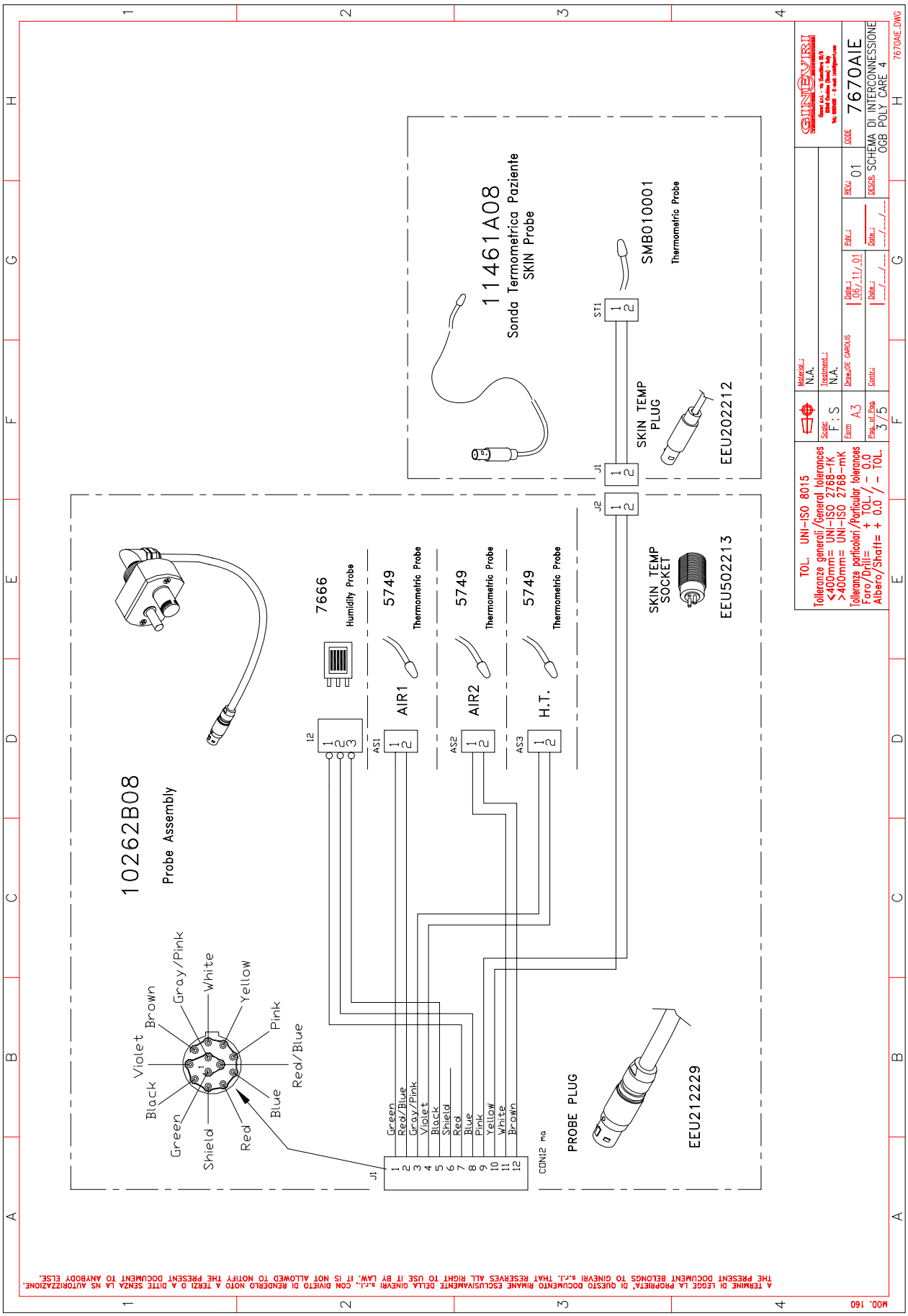
OXYGEN CALIBRATION

28 Connect the oxygen reference simulator to the proper connectors placed on the control panel, and set it on ZERO.
29 Set the multimeter on mV cc and connect the negative terminal on pin 2 of J5 and the positive terminal on pin 6 of U12 of the microprocessor board. Adjust the trimmer PT4 of the display board until the measured voltage is 0mV ± 2mV. If necessary adjust the trimmer PT3 on the display board previously.
30 Set the oxygen reference simulator on OXI% = 21% and adjust PT3 until the value measured by the multimeter is 980mV ± 5mV.
31 Set the oxygen reference simulator on OXI% = CAL and check that after this value is hold for about 30 sec. from the CAL indication, the OXI display shows the value 21.
32 Set the oxygen reference simulator on OXI% = 98% and adjust PT3 until the value shown on the OXI display is 98.
33 Set the oxygen reference simulator on OXI% = 21% and check that the value shown on the OXI display is 21. If any deviation is present, then repeat steps 28 to 33 until the values 21% e 98% are obtained.

2. ELECTRICAL WIRING DIAGRAM






10262B08
Probe Assembly
11461A08
Sonda Termometrica Paziente
SKIN Probe
SMB010001
Thermometric Probe
SKIN TEMP
PLUG
EEU202212
SKIN TEMP
SOCKET
EEU502213
PROBE PLUG
EEU212229
7666
Humidity Probe
5749
Thermometric Probe
AIR1
AIR2
H.T.
Violet
Brown
Gray/Pink
White
Yellow
Pink
Red/Blue
Black
Green
Shield
Red
Blue
J1
J2
J3
J4
AS1
AS2
AS3
ST1
CDN12 mo
TOL. UNI-ISO 8015
Tolleranze generali /General tolerances
<400mm= UNI-ISO 2768-fK
>400mm= UNI-ISO 2768-mK
Tolleranza particolari /Particular tolerances
Foro/Drill= + TOL. / - 0.0
Albero/Shaft= + 0.0 / - TOL.
Material :
N.A.
Treatment :
N.A.
Scale:
F. S
Form
A3
Page of Pag.
3 / 5
Drawn:
DOE CAROLUS
Date :
06/11/01
Date :
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Date :
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Date :
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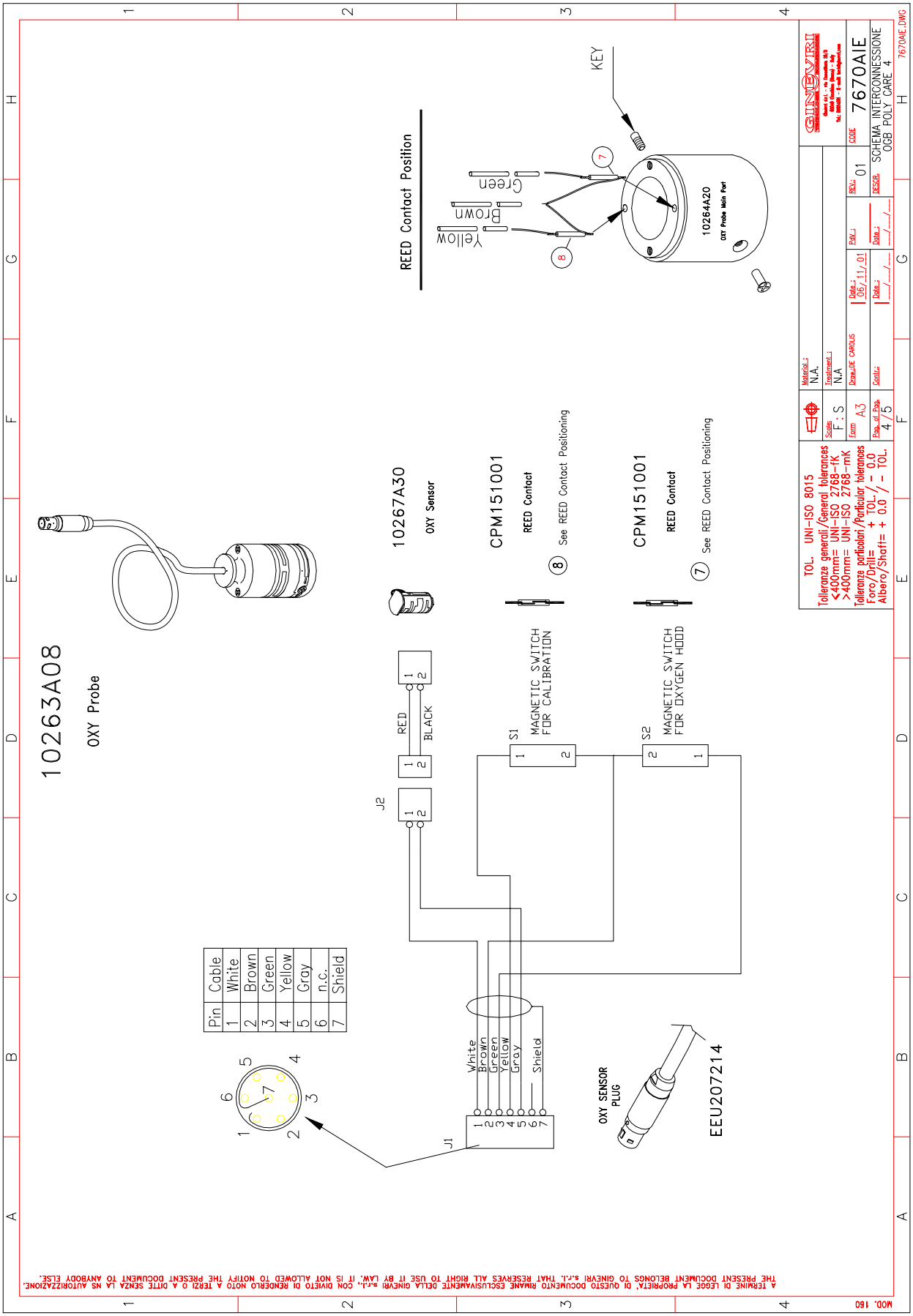
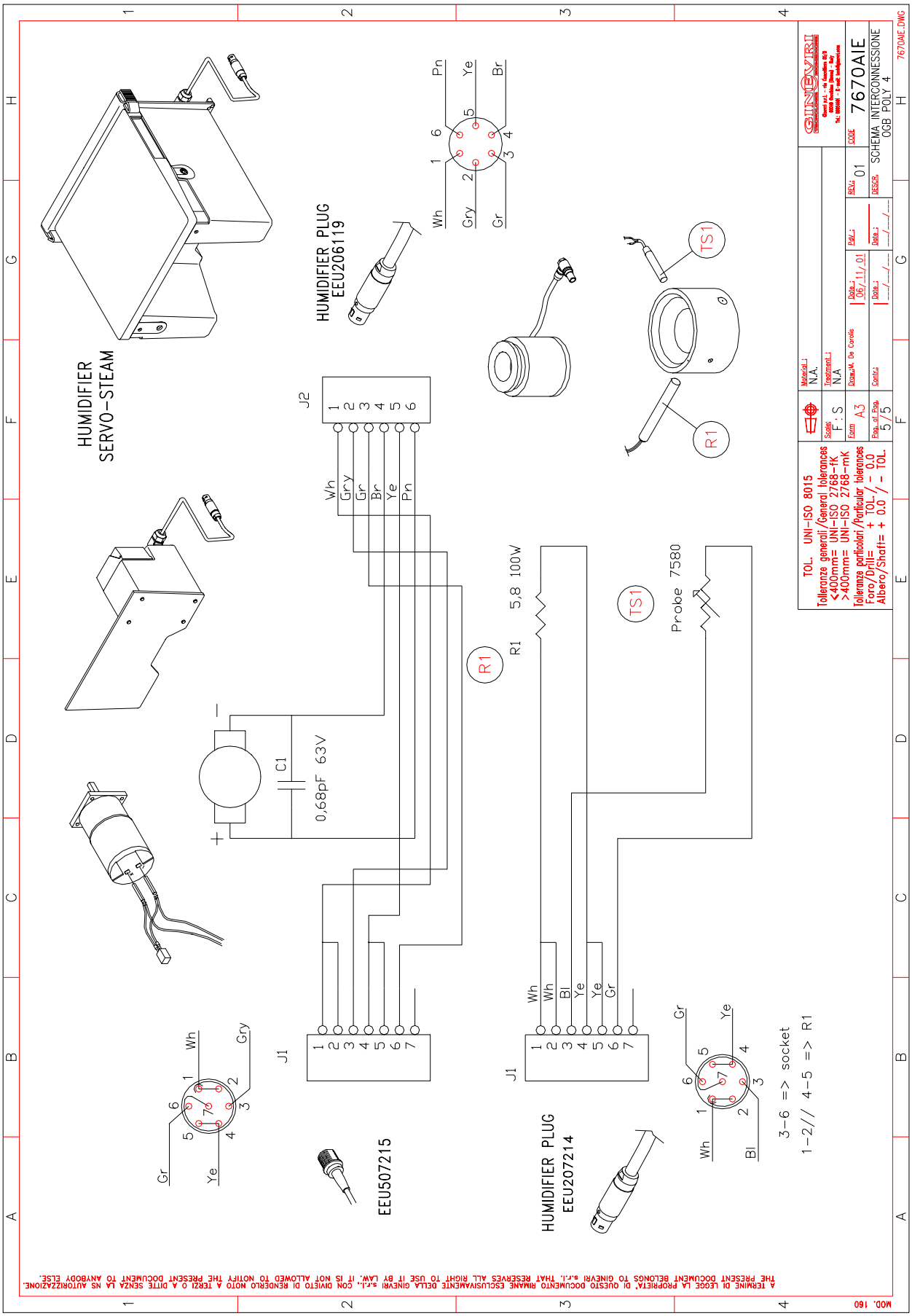
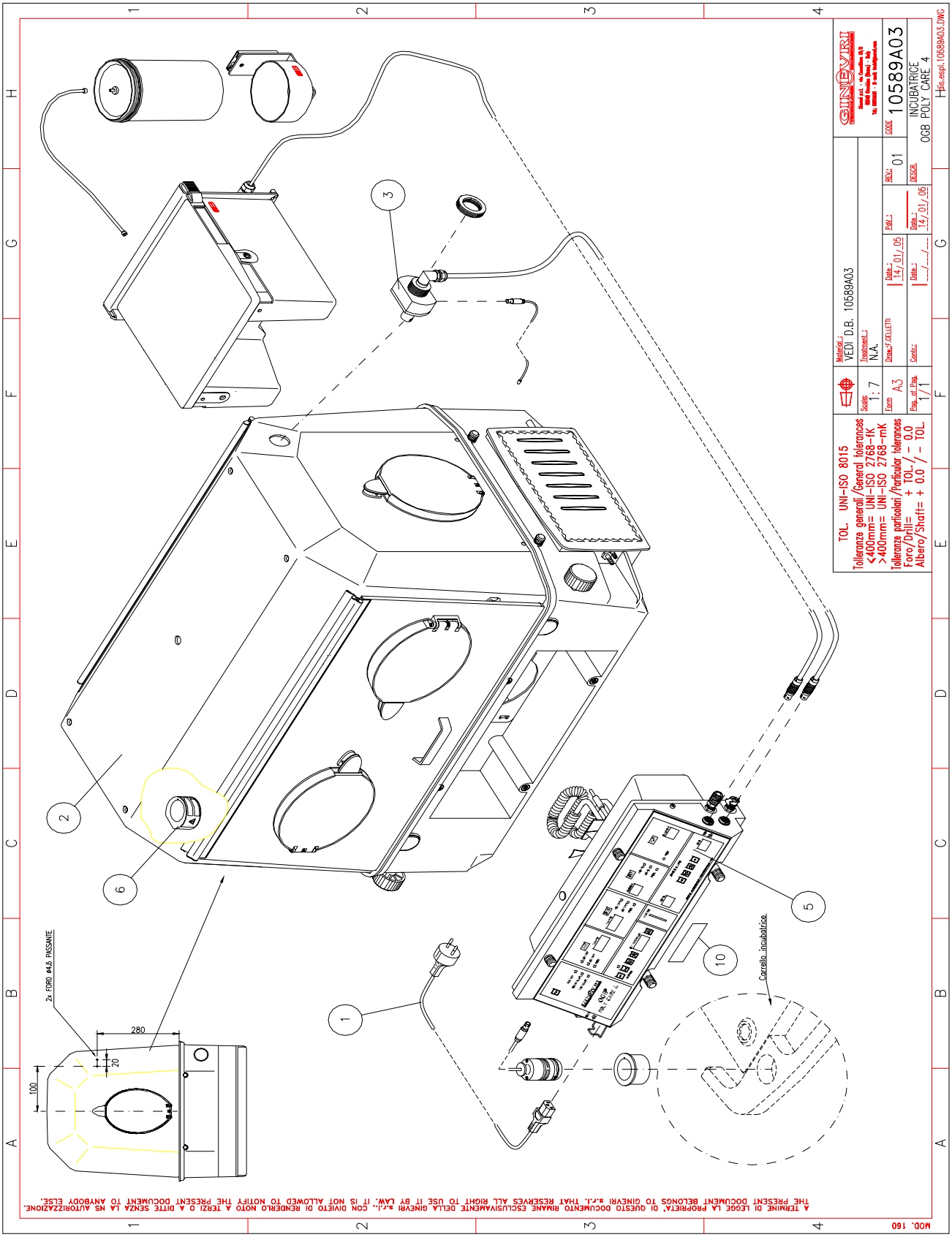
REV.: 01
DESCR. SCHEMA DI INTERCONNESSIONE
OGB POLY CARE 4
CODE 7670AIE
7670AIE.DWG
MOD. 160





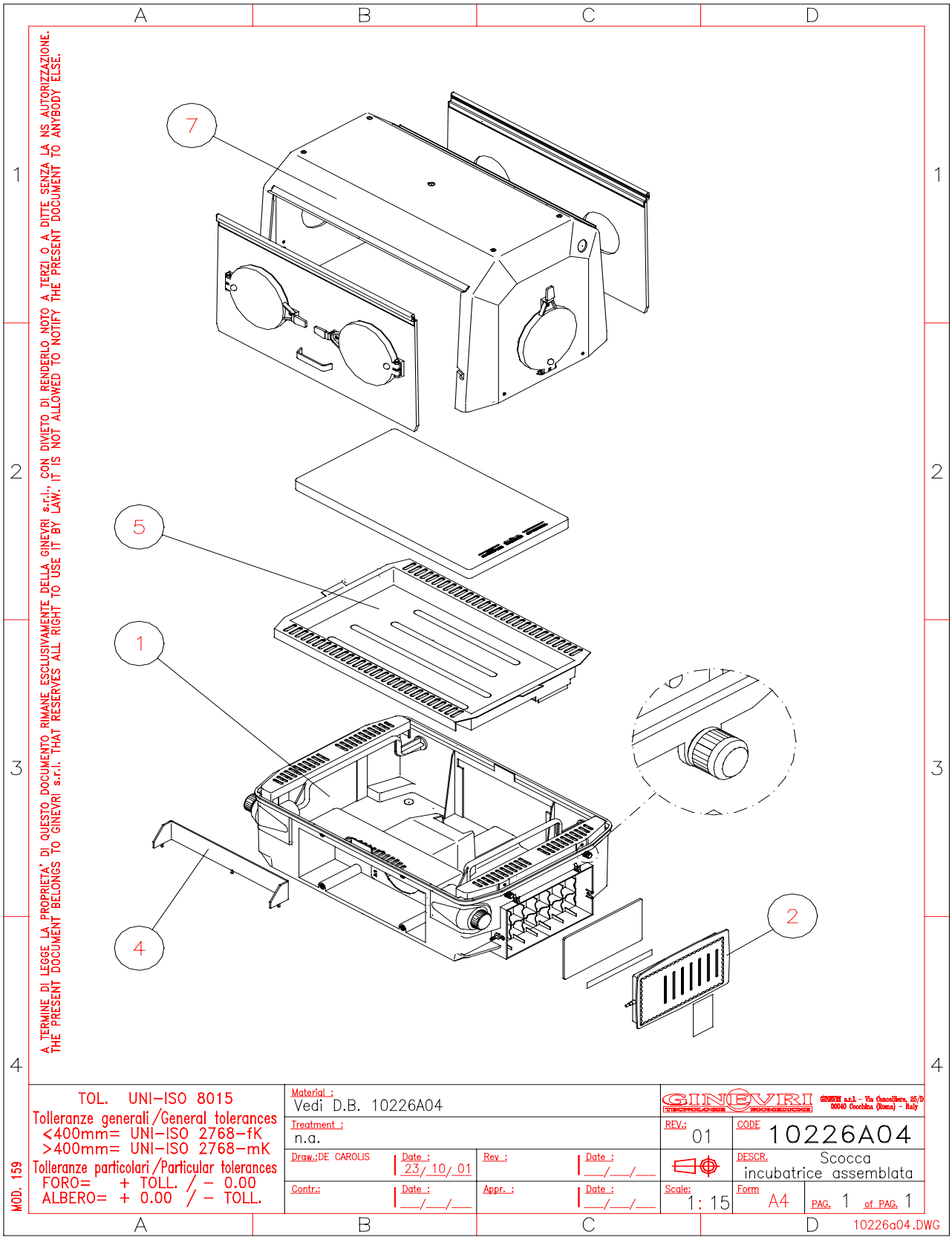
3. SPARE PARTS

3.1. INCUBATOR OGB POLY 4 (code 10589A03)



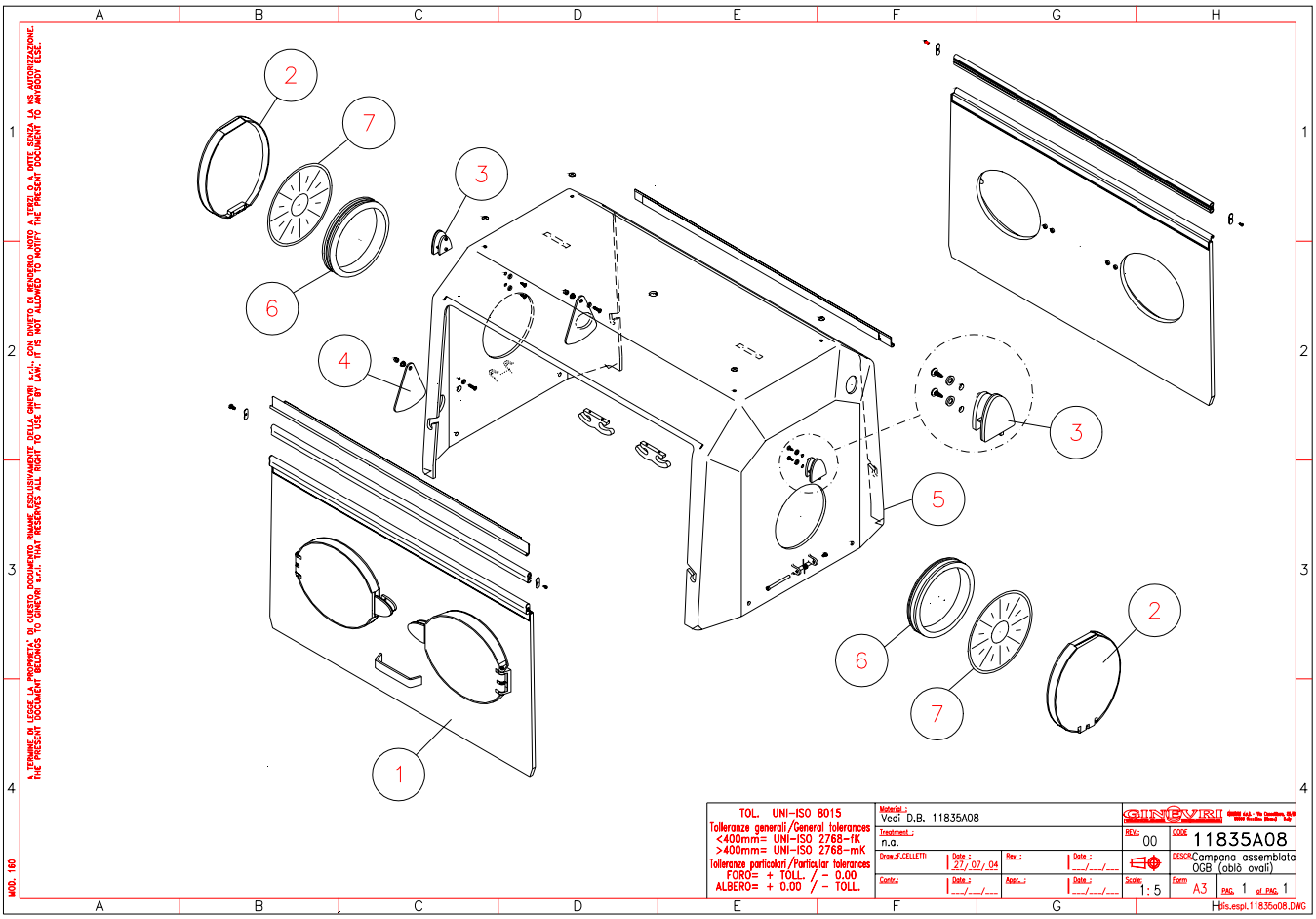
Ref.	***Code***	***Description***	***Q.ty***
10	11885A72	ELECTRIC CABLE SCHUKO – IEC	NR. 1
1	10226A72	INCUBATOR BODY	NR 1
3	10262B72	PROBE ASSEMBLY	NR 1
5	10285A72	CONTROL PANEL POLY 4	NR 1
6	10388A72	OXY SENSOR CALIBRATION SUPPORT	NR 1
13	10388B72	OXY SENSOR HOOD SUPPORT	NR. 1
2	7424A72	SERVO STEAM HUMIDIFIER POLY4	NR 1

3.2. INCUBATOR BODY ASSEMBLY (code 10226A04)



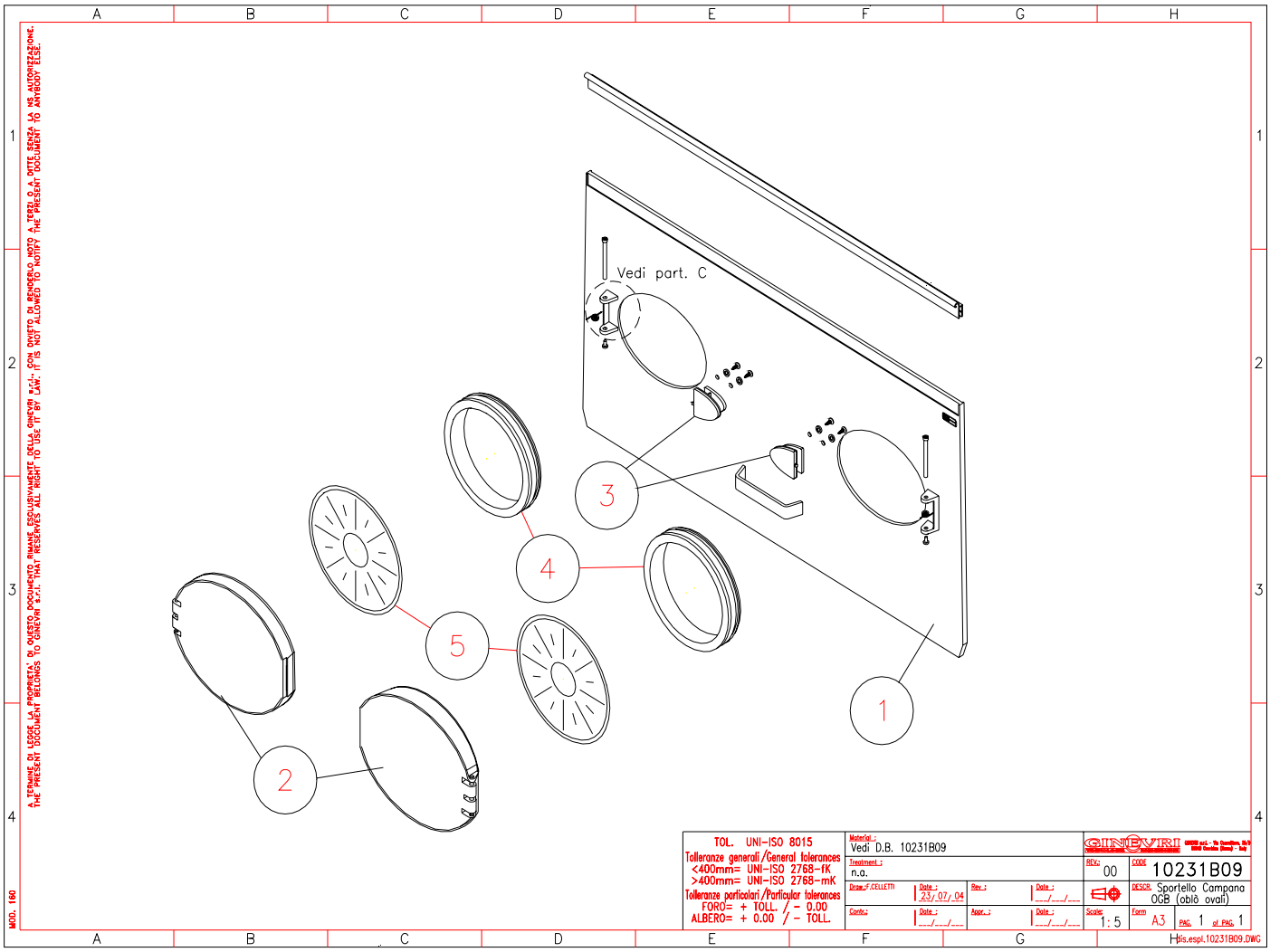
Ref.	***Code***	***Description***	***Q.ty***
1	10106A72	COMPLETE BASE OGB	1
2	11315A72	MICROFILTER PANEL	1
5	6100A72	PATIENT TRAY OGB CEI	1
4	7320A72	AIR CONVEYOR LEXAN	1
7	11835A72	INCUBATOR HOOD	1

3.3. INCUBATOR HOOD ASSEMBLY (code 11835A08)



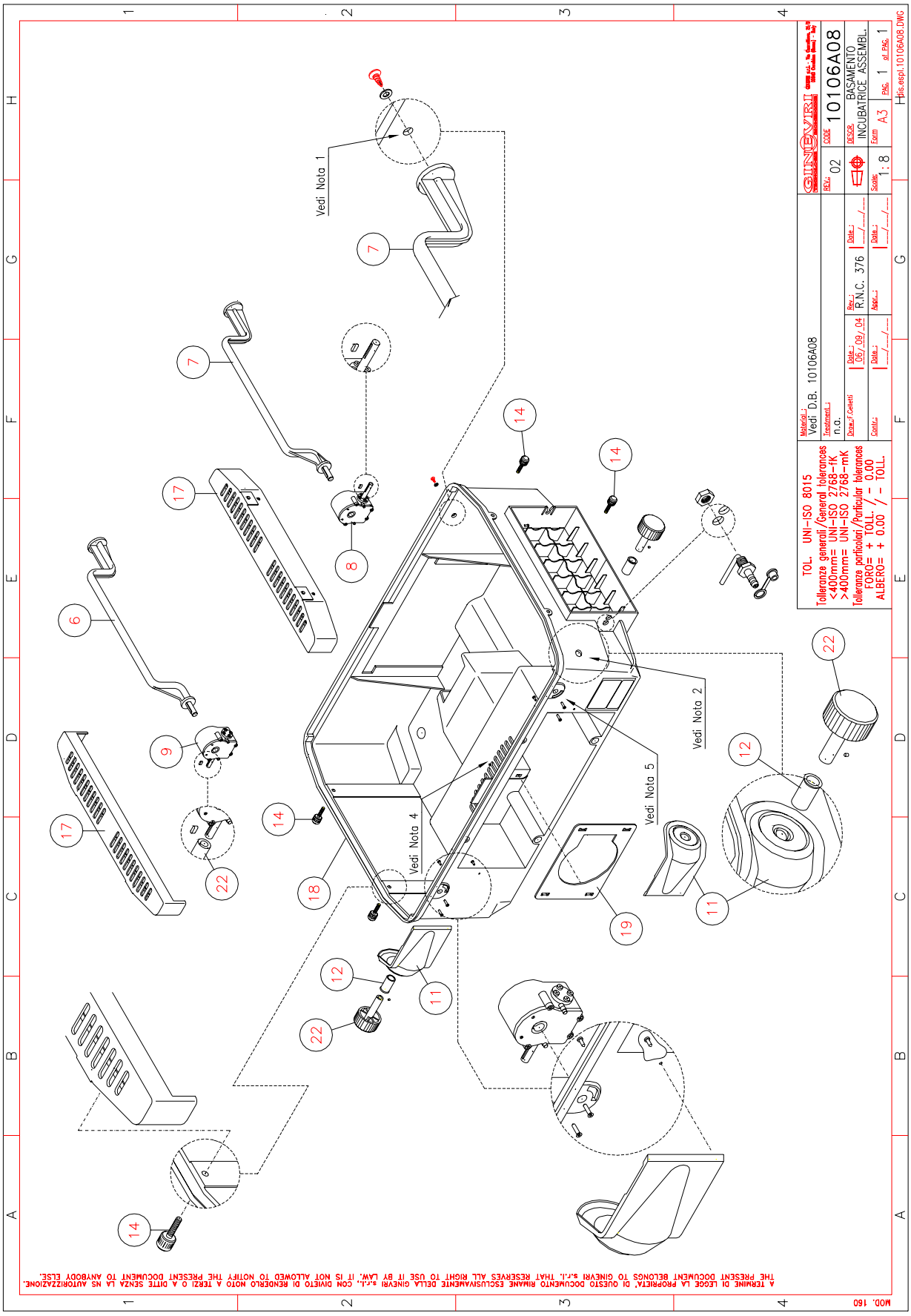
Ref.	Code	Description	Qty
1	10231B72	HOOD DOOR PANEL OVAL PORT ASSEMBLY	1
2	11745A72	OGB INCUBATOR OVAL PORTHOLE	2
3	11750A72	PUSH OPENERS FOR ACCESS PORTS	6
4	2592A72	TRIANGLE FOR OGB	2
5	7460A72	OGB INCUBATOR HOOD LEXAN N/MOD	1
6	12029A73	RUBBER SEAL FOR THE HOOD (ROUND HOLES)	6
7	11725A73	SLEEVE FOR PORTHOLE	12

3.4. HOOD DOOR ASSEMBLY (code 10231B09)



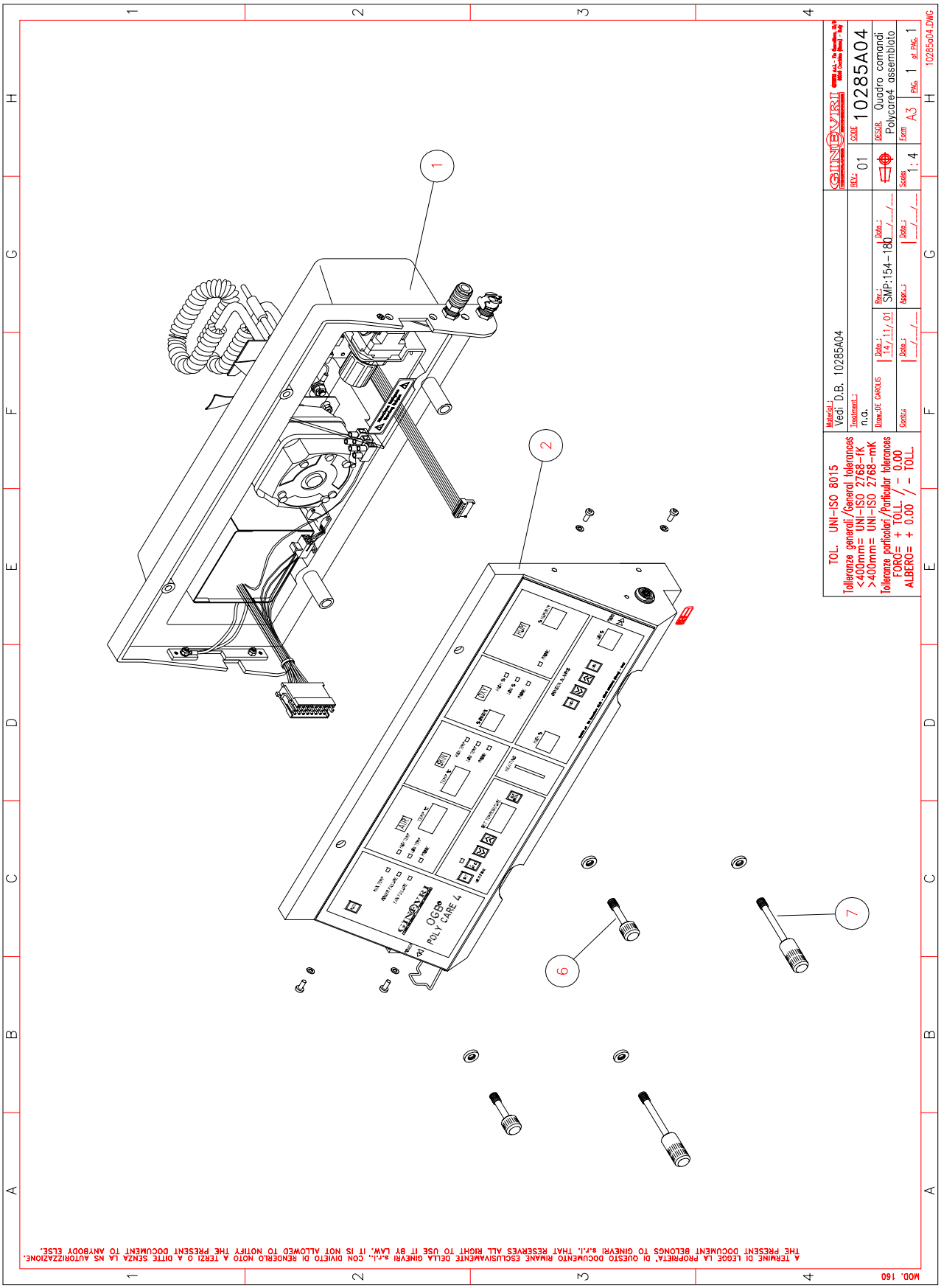
Ref.	Code	Description	Qty
1	11744A72	OGB INCUB. DOOR WITH OVAL PORTS	1
2	11745A72	OVAL ACCESS PORTS OGB INCUB.	2
3	11750A72	PUSH OPENERS FOR ACCESS PORTS	6
4	11721A73	RUBBER SEAL FOR DOORS WITH OVAL PORTHOLES	6
5	11725A73	SLEEVE FOR PORTHOLE	12

3.5. BASE ASSEMBLY (code 10106A08)



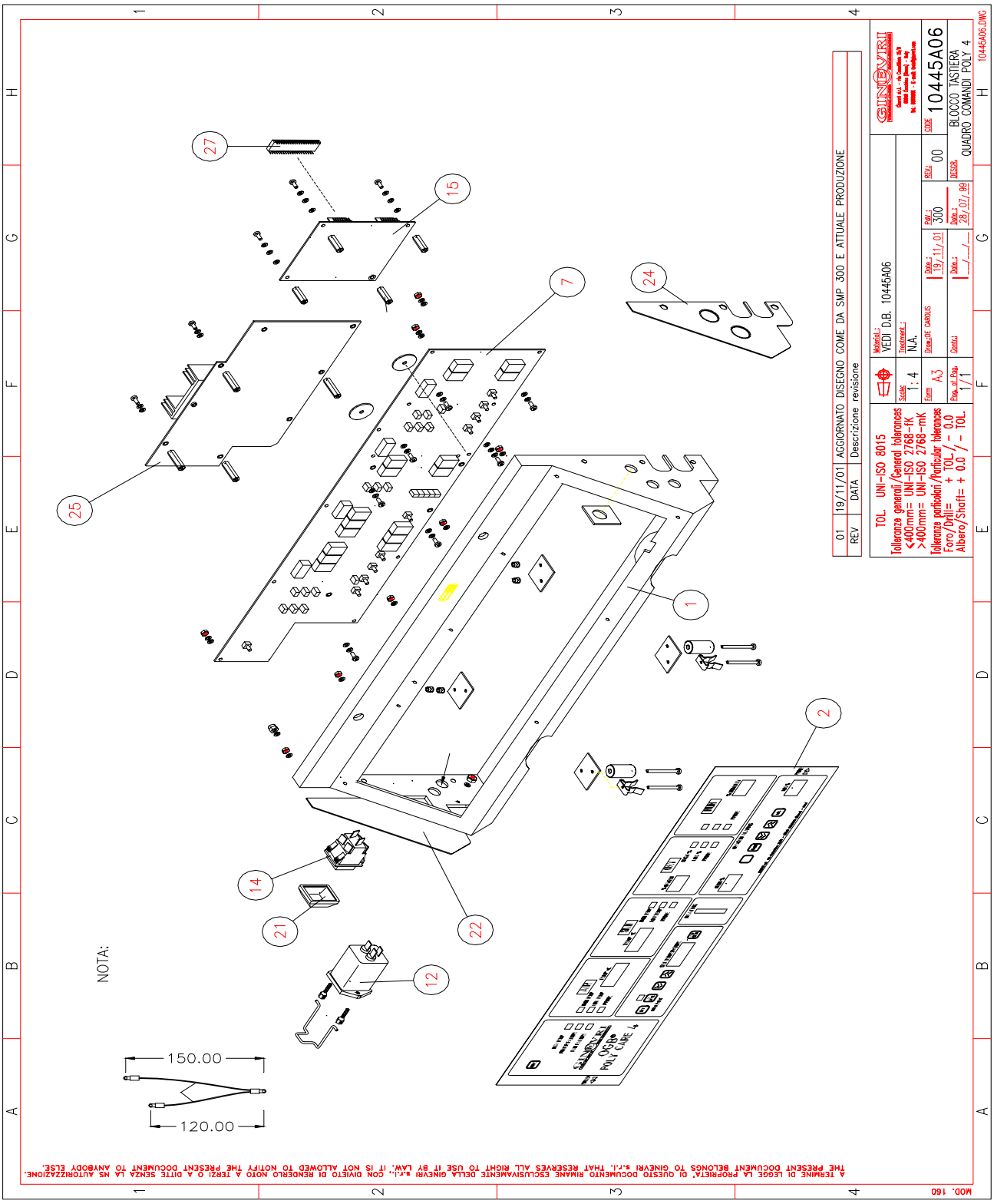
Ref.	*Code*	*Description*	*Q.ty*
6	10107A72	TRAY POSITIONING LEVER LEFT	NR 1
7	10108A72	TRAY POSITIONING LEVER RIGHT	NR 1
8	10244A72	SMOOTH TILT LEFT	NR 1
9	10245A72	SMOOTH TILT RIGHT	NR 1
11	10744A72	SMOOTH-TILT KNOB CASE	NR 2
12	10745A72	SMOOTH TILT KNOB PASSING BEARING	NR 2
14	1660A72	KNOB M6X25	NR 4
17	453A72	HOLED LONGERON X OGB	NR 2
18	5846A72	BASE OGB LEXAN	NR 1
19	5932A72	ORIFICE PLATE OGB/2000 LEXAN	NR 1
22	7702A72	KNOB D50 X SHAFT D8	NR 2

3.6. CONTROL PANEL ASSEMBLY (code 10285A04)



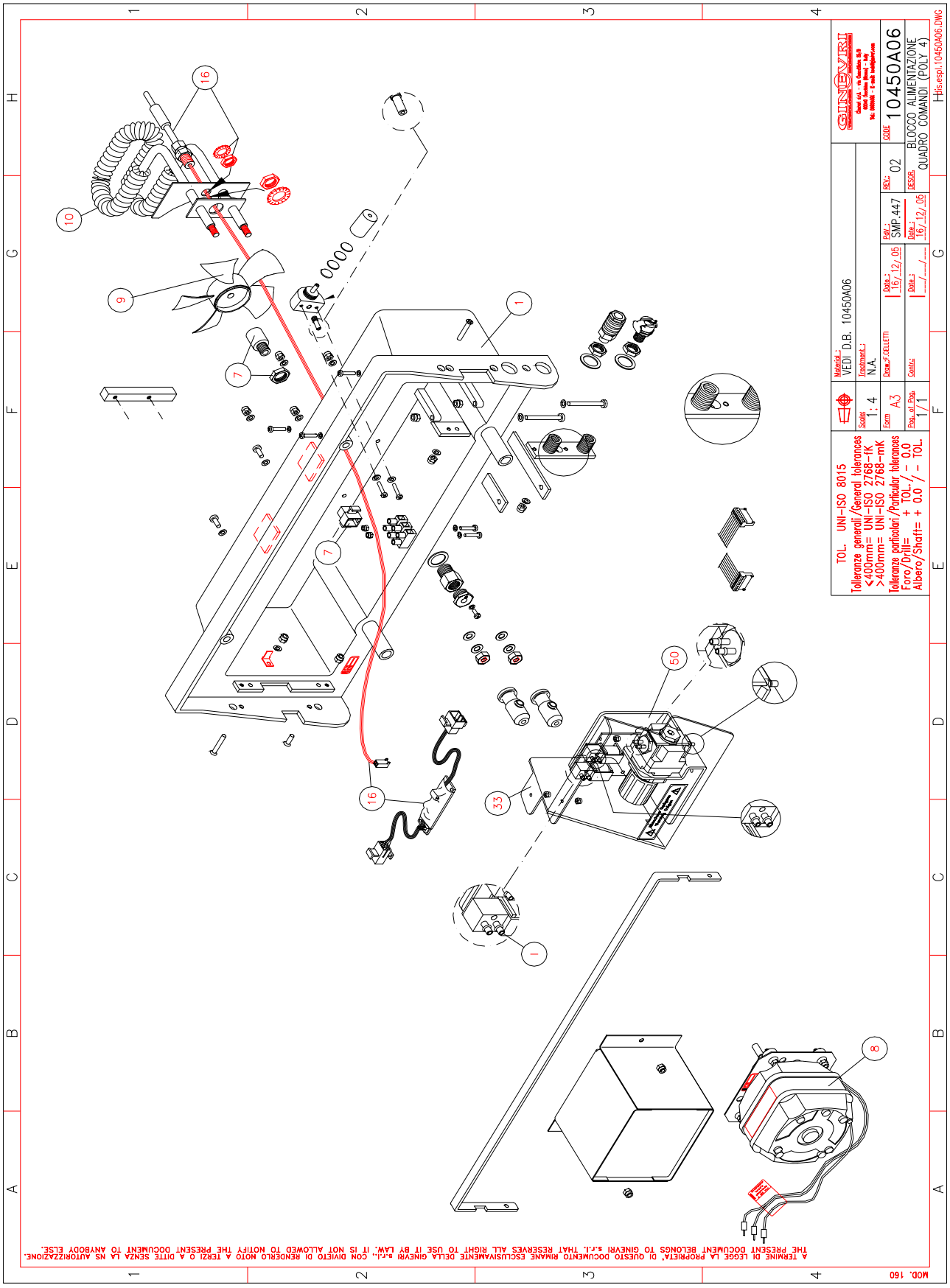
Ref.	***Code***	***Description***	***Q.ty***
3	10231B72	HOOD DOOR WITH OVAL PORTHOLES	2
7	11745A72	OVAL PORTHOLE OGB	2
8	11750A72	PUSH FOR OGB	2
11	2592A72	TRIANGLE FOR OGB	2
20	7460A72	HOOD OGB INC. LEXAN N/MOD	1

3.7. CONTROL PANEL - KEYBOARD BLOCK (code 10445A06)



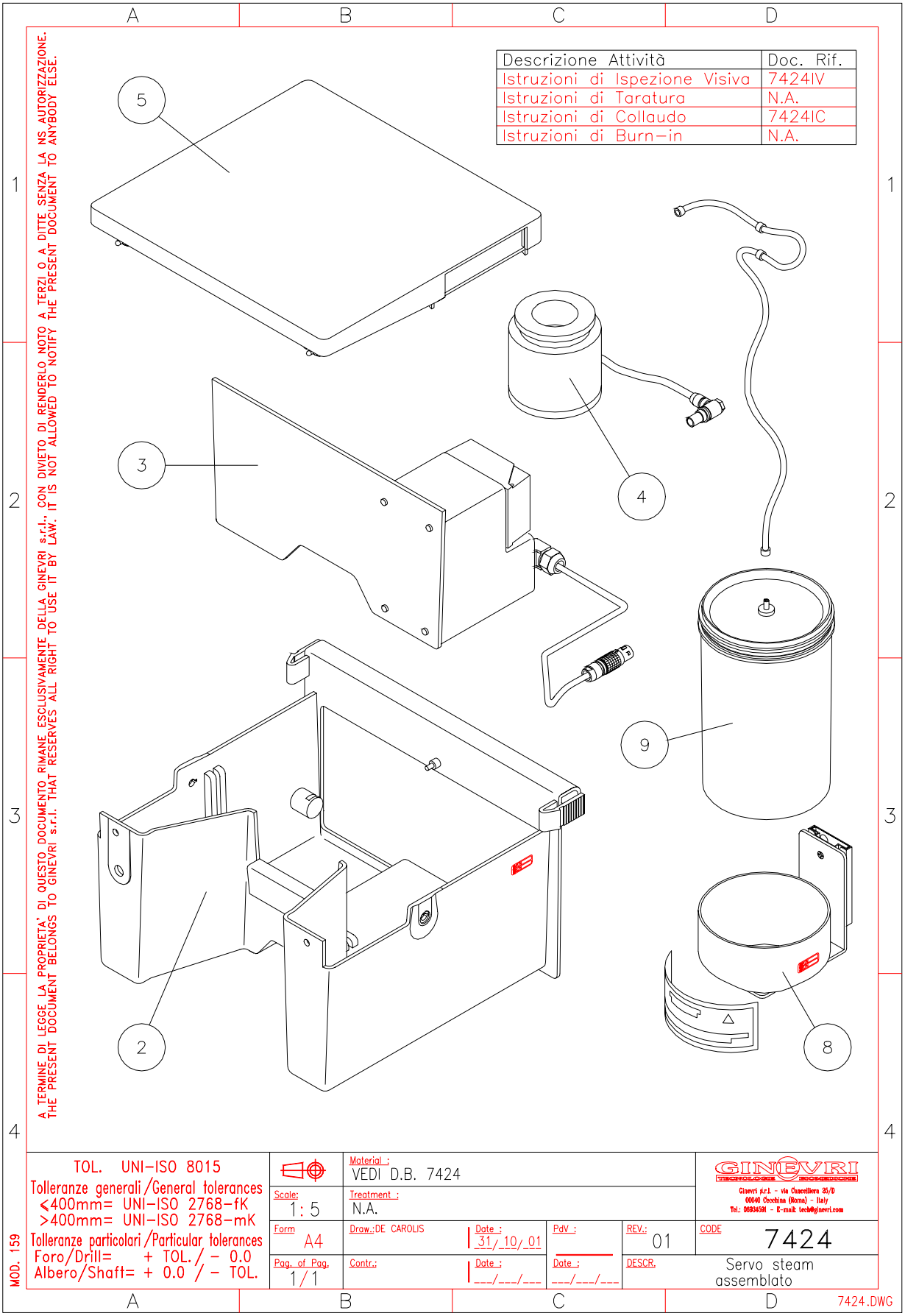
Ref.	Code	Description	Q.ty
12	11888A72	SOCKET WITH IEC FILTER 4A	NR. 1
7	10348A72	CONTROL BOARD	NR. 1
27	10405A72	EPROM	NR. 1
21	10531A72	SWITCH PROTECTION 30X24	NR. 1
22	10663A72	LABEL LEFT SIDE CONTROL PANEL	NR. 1
24	10664A72	LABEL RIGHT SIDE CONTROL PANEL	NR. 1
2	10723A72	MEMBRANE KEYBOARD	NR. 1
25	11216A72	POWER BOARD	NR. 1
15	11219A72	MICROPROCESSOR BOARD	NR. 1
1	122A72	FRONT PANEL	NR. 1
14	6422A72	GREEN SWITCH ON/OFF	NR. 1

3.8. CONTROL PANEL - POWER BLOCK (code 10450A06)



Ref.	*Code*	*Description*		*Q.ty*
33	10585A72	OXYGEN CASE POLY 4	NR	1
50	10774A72	PRESSURE REDUCTOR POLY 4	NR	1
16	11134A72	SAFETY THERMOSTAT ASSEMBLY	NR	1
8	11233A72	MOTOR ASSEMBLY	NR	1
9	4906A72	FAN	NR	1
1	5848A72	CONTROL PANEL INTERNAL BODY	NR	1
7	6912A72	PHOTOCOUPLER W/SUPPORT	NR	1
10	7475A72	RESISTANCE 300W 220V FOR OGB	NR	1

3.9. SERVO STEAM HUMIDIFIER (code 7424)



Item	*Code*	*Description*	*Q.ty*
2	10602A72	SERVO STEAM ASSEMBLED BASIN	NR 1
3	10603A72	PERISTALTIC PUMP ASSEMBLY	NR 1
4	10604A72	VAPORIZER ASSEMBLY	NR 1
5	10605A72	SERVO-STEAM BASIN COVER	NR 1
8	11003A72	TANK SUPPORT LT. 1,5	NR 1
9	11004A72	WATER TANK LT. 1,5	NR 1

4. MAINTENANCE SERVICE

Ginevri representative in your country can stipulate, within one month before warranty period expiry, various kinds of maintenance contract.

For any inquiry please contact us:

Ginevri s.r.l.
Via Cancelliera, 25/B
00040 Cecchina (Roma)
Italy
Tel. +39 06 93459331
Fax. +39 06 93459393

The device is manufactured in compliance with the standards CEI 62.5 (file 1445 of 01/91) and EN 60 601-1 and related IEC 601-2-50. Moreover the device is provided with an EMC (electromagnetic compatibility) anti-jamming device.

If servicing/maintenance after warranty period is performed by other companies not qualified/authorized by us, all fixed parts have to be marked by the repairer. The repairer has to verify and guarantee in writing the perfect functioning of the device. Any modification of the device must comply with the Medical Devices Normative law 93/42/CEE and approved by Ginevri s.r.l.

For maintenance service original materials must be used.

5. PROGRAMMED AND PREVENTIVE MAINTENANCE

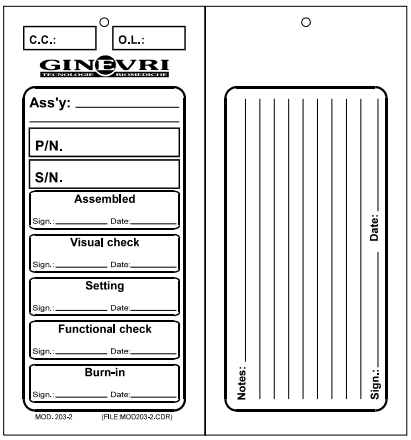
All electromedical devices must be maintained regularly, as for the normative law (CEI 1276 G).
The aim of preventive and programmed maintenance is to minimise the need of faults repairing and to obtain:

- **Correct functioning;**
- **Safety for the patient, the operator and the surrounding environment;**
- **Maximum availability of the device.**

Preventive maintenance consists in controls performed by the operator and periodical maintenance. Written programs should be defined regarding every kind of device, based on laws, technical standards and suggestions of the manufacturer. These programs must include controls performed by the operators and periodical maintenance.

6. FINAL CHECK

If all test operations are successfully completed, sign and stamp the Functional-Check field and tick the Setting field of the label attached to the device, as shown in the following picture.



If test operations are not successfully completed, state whether the OGB Polycare 4 Infant Incubator has to be repaired or replaced. In case it has to be repaired, this can be done immediately (urgent cases) or afterwards. If the maintenance can be performed afterwards, place a red mark on the device and leave it in the area dedicated to materials waiting for maintenance for a further service. Write down the anomalies in the Notes field on the back of the label.
If the OGB Polycare 4 Infant Incubator has to be replaced, fill in the non-conformity statement, according to PO-10.

7. TECHNICAL DATA

FRAME	***POLYCARBONATE***
POWER SUPPLY	***220V 50/60 HZ***
POWER DRAIN	***440W (540W HOT SPOT)***
SAFETY CLASS	***I***
CATEGORY	***B***
GROUND DISPERSION CURRENT	***70 µ A***
ELECTRICAL PROTECTION	***2 FUSES 5X20MM 3.15 AMP F***
POWER FAILURE ALARM BATTERY	***INCLUSA***
SKIN TEMPERATURE DISPLAY	***0.1°C RESOLUTION, 0.3°C MAX ERROR***
AIR TEMPERATURE DISPLAY	***0.1°C RESOLUTION, 0.6°C MAX ERROR***
HIGH TEMPERATURE ALARM	***(only Automatic mode) ACOUSTIC/VISUAL AUTOMATIC (+1°C with respect to SET TEMP)***
ENVIRONMENT OPTIMUM TEMPERATURE	***21°C /26°C***
STORAGE TEMPERATURE	***-10°C/+50°C***
MAXIMUM WHEIGHT ON PATIENT BED	***10 KG***
MAXIMUM DIMENSIONS	***81X62X69cm***
WHEIGHT	***51 kg***

UNI EN ISO 9000:2000 – CERTIFIED QUALITY SYSTEM BY IQNET – No. CERT –IT-37100
UNI CEI EN 46001 – PARTICULAR REQUIREMENTS FOR MEDICAL DEVICES

CE 0051

CSQ

MED

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THE INTERNATIONAL CERTIFICATION NETWORK

www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO N.
CERTIFICATE N. **9124.GIN2**

SI CERTIFICA CHE IL SISTEMA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY SYSTEM OPERATED BY

GINEVRI SRL

VIA GIACOMO BONI, 15 - 00162 ROMA (RM)

UNITA' OPERATIVE
OPERATIVE UNITS

VIA CANCELLIERA 25/D - 00040 CECCHINA STAZIONE (RM)

E' CONFORME ALLA NORMA
IS IN COMPLIANCE WITH THE STANDARD

EN 46001
ISO 13485:1996

PER LE SEGUENTI ATTIVITA'
FOR THE FOLLOWING ACTIVITIES

Progettazione, produzione, installazione e manutenzione di apparecchiature elettromedicali per assistenza neonatale e pediatrica
Design, manufacture, installation and maintenance of electromedical equipment for neonatal and pediatric care

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI QUALITA' E DI GESTIONE DELLE AZIENDE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR THE CERTIFICATION OF COMPANY QUALITY AND MANAGEMENT SYSTEMS

PRIMA EMISSIONE	EMISSIONE CORRENTE
FIRST ISSUE	*CURRENT ISSUE*
2004-04-23	

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale

CISQ is the Italian Federation of management system Certification Bodies

SINCERT EA: 19

SQ N°0034, SGA N°0002, SCR N°0005, SSI N°0030, PRD N°0059

Membro degli Accordi di Mutuo Riconoscimento EA e IAF Signatory of EA and IAF Mutual Recognition Agreement

La validità del presente certificato è subordinata a sorveglianza annuale e al riesame completo del Sistema di Qualità con periodicità triennale secondo le procedure dell'IMQ

The validity of the certificate is submitted to annual audit and a reassessment of the entire Quality System within three years according to IMQ rules

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